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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,319	11/27/2000	Dale B. Schenk	15270J-004743US	6653

20350 7590 07/21/2003

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EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	**PAPER NUMBER**
1647	17

DATE MAILED: 07/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,319	SCHENK, DALE B.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52,54-83,85,86,89,92-94,97,99 and 101-163* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-52,54-83,85,86,89,92-94,97,99 and 101-163.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Preliminary Amendments filed 20 August 2001 (Paper No. 4), 27 August 2001 (Paper No. 9), and 30 August 2002 (Paper No. 16) have been received and entered in full. Claims 56-163 have been added. Claims 53, 84, 87, 88, 90, 91, 95, 96, 98, and 100 have been cancelled. Claim 99 has been amended. Claims 1-52, 54-83, 85, 86, 89, 92-94, 97, 99, and 101-163 are under examination.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-32** and **35-37** (each in part), drawn to a method of preventing or treating a disease characterized by amyloid deposit in a patient comprising *administering an effective dosage of an antibody* that specifically binds to the amyloid deposit or a component thereof to the patient, classified in class 424, subclass 130.1, for example.

II. Claims **1-37** (each in part), drawn to a method of preventing or treating a disease characterized by amyloid deposit in a patient comprising administering an effective dosage of an antibody that specifically binds to the amyloid deposit or a component thereof to the patient wherein the method further comprises *administering a polynucleotide* to said patient, classified in class 514, subclass 44, for example.

III. Claims **38-52**, drawn to a method of preventing or treating Alzheimer's disease, comprising *administering an effective dosage of a polypeptide comprising an*

active fragment of Aβ that induces an immune response to Aβ in a patient, classified in class 514, subclass 2, for example.

IV. Claims **54-55**, drawn to a method of screening an antibody to Aβ or an active fragment of Aβ for use in treatment of Alzheimer's disease, comprising administering an antibody that specifically binds to Aβ or a fragment of Aβ to a *transgenic animal* disposed to develop characteristics of Alzheimer's disease, classified in class 800, subclass 3, for example.

V. Claims **56-82, 85-86, 89,** and **92-94**, drawn to a method of preventing or treating a disease characterized by amyloid deposit in a patient, comprising administering an effective dosage of an antibody that specifically binds to the amyloid deposit or a component thereof to the patient *wherein the antibody specifically binds to an epitope within residues 13-28 of Aβ,* classified in class 424, subclass 130.1, for example.

VI. Claims **97** and **99**, drawn to a pharmaceutical composition of an *antibody specifically binds to an epitope within residues 13-28 of Aβ,* classified in class 530, subclass 387.1, for example.

VII. Claims **101-129** and **137**, drawn to a *humanized antibody* that specifically binds an epitope contained with positions 13-28 of Aβ and pharmaceutical compositions thereof, classified in class 530, subclass 387.1, for example.

VIII. Claims **130-136**, drawn to a *nucleic acid*, comprising a sequence coding for the light chain or the heavy chain of the humanized antibody of any one of claims

101-129, or a fragment thereof, expression vectors, and host cells comprising same, classified in class 435, subclass 69.1, for example.

IX. Claims **138-150**, drawn to a method to inhibit or reduce amyloid plaques in humans, comprising administering to a human subject in need of such reduction an effective amount of a *humanized antibody or fragment thereof which specifically immunoreacts with an epitope contained in positions 13-28 of Aβ*, classified in class 424, subclass 130.1, for example.

X. Claims **151-162**, drawn to a method of *treating cognitive decline* in a subject comprising administering to the subject an effective amount of a humanized antibody or fragment of any one of claims 101-129, classified in class 424, subclass 130.1, for example.

XI. Claim **163**, drawn to a method of *treating Alzheimer's disease* comprising administering to a patient in need thereof an effective amount of the antibody or fragment of any one of claims 101-129, classified in class 424, subclass 130.1, for example.

3. The inventions are distinct, each from the other because of the following reasons:

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, III, IV, V, IX, X, and XI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of administering an effective dosage of an antibody to prevent

a disease characterized by amyloid deposits, which is not required by any of the other Inventions. Invention II requires search and consideration of administering a polynucleotide to prevent a disease characterized by amyloid deposits, which is not required by any of the other Inventions. Invention III requires search and consideration of administering an effective dosage of polypeptide to prevent Alzheimer's disease, which is not required by any of the other Inventions. Invention IV requires search and consideration of using a transgenic animal in a screening method, which is not required by any of the other Inventions. Invention V requires search and consideration of administering an effective dosage of an antibody that binds to an epitope within residues 13-28 of Aβ to prevent a disease characterized by amyloid deposits, which is not required by any of the other Inventions. Invention IX requires search and consideration of a method to inhibit or reduce amyloid plaques in humans comprising administering an effective dosage of an antibody that binds to an epitope within residues 13-28 of Aβ, which is not required by any of the other Inventions. Invention X requires search and consideration of treating cognitive decline, which is not required by any of the other Inventions. Invention XI requires search and consideration of treating Alzheimer's disease comprising administering to a patient in need thereof an effective amount of the antibody or fragment of any one of claims 101-129, which is not required by any of the other Inventions.

5. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions VI, VII, and VIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably

distinct. The antibody of Invention VI is not required to make or use the humanized antibody of Invention VII. Nor is the humanized antibody of Invention VII is not required to make or use the antibody of Invention VI. The antibody of Invention VI can be prepared by processes which are materially different from recombinant DNA expression of Invention VIII, such as by chemical synthesis, or by isolation and purification from natural sources. The humanized antibody of Invention VII can be prepared by processes which are materially different from recombinant DNA expression of Invention VIII, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the nucleic acid of Invention VIII can be used other than to make the antibodies of Inventions VI or VII, such in gene therapy or as a probe in nucleic acid hybridization assays.

6. Inventions VI and each of I, IV, and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention VI can be used to purify Aβ in a biochemical assay.

7. Inventions VII and each of IV, IX, X, and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention VII can be used to purify Aβ in a biochemical assay.

8. Inventions VIII and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Invention VIII can be used to make antibodies *in vitro* or in a hybridization (screening) assay.

9. Inventions VI and each of II, III, IX, X, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and each of II, III, IX, X, and XI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II, III, IX, X, and XI do not recite the use or production of the *antibody* of Invention VI.

10. Inventions VII and each of I, II, III, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and each of I, II, III, and V are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II, III, and V do not recite the use or production of the *humanized antibody* of Invention VII.

11. Inventions VIII and each of I, III, IV, V, IX, X, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VIII and each of I, III, IV, V, IX, X, and XI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, III, IV, V, IX, X, and XI do not recite the use or production of the *nucleic acid* of Invention VIII.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
July 18, 2003

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600